Complete Final Version of the Certificate of Analysis

(02-0898)

Dr. Kimberly Spence

Title: Precursor Preference in Surfactant Synthesis of Newborns

Cambridge Isotope Laboratories, Inc.

50 Frontage Road, Andover, MA 01810-5413 USA
PH: 800.322.1174 (USA) PH: 978.749.8000
FAX: 978.749.2768 URL: http://www.isotope.com

Certificate of Analysis

Product: Sodium Acetate (1-^{13}C, 99%)
Grade: Metabolic
Catalog #: CLM-156-MG
Formula: CH_3*COONa
Molecular Weight: 83.03
CAS # : [23424-28-4]
Batch # : PR-12777
Production Completed: 09/06/01

Method of Analysis

Test	Reference/Method	Specification	Results
Appearance	USP 23	White, crystalline solid	Pass
Identification	^{1}H-NMR	Conforming	Pass
	^{13}C-NMR	Conforming	Pass
Chemical Purity	Titration	98-101%	99.2%
Isotopic Purity	GC/MS	≥ 99 atom%	98.7%
Bioburden	USP/Sterility	Sterile	Pass
Endotoxin	USP/Pyrogen-Rabbit	USP 23 <151>	Pass
	USP/Pyrogen-LAL	≤ 0.03 EU/mg	< 0.002 EU/mg
Heavy Metals	USP/ASTM	≤ 10 ppm	< 10 ppm
pH	CIL	7.5 - 9.2	9.2
Water Content	Karl-Fischer	≤ 1%	0.66%
Clarity of Solution (50 mg/ ml)	CIL	Clear	Pass

Product should be stored in a cool, dry place away from light.

Certified:

Eloise C. Young

Eloise C. Young Ph.D., Technical Service Chemist

September 21, 200

Date

Version 1.0 (Updated 3/31/99)

ISOTEC
A MEMBER OF THE SIGMA-ALDRICH FAMILY

CERTIFICATE OF ANALYSIS

DATE 02/10/2004

Hexadecanoic Acid-1,2,3,4-$^{13}C_4$, Potassium Salt (Potassium palmitate)

ISOTEC NUMBER T83-42081 ALDRICH NUMBER 605808 BATCH NUMBER CR1261

METHODS	SPECIFICATIONS	TEST RESULTS
% Water	< = 1%	0.95%
^{1}H-NMR (FT)	Structure and purity verification	Meets requirement
^{1}H-NMR (FT)	Minimum 99 atom% ^{13}C	99.0 atom% ^{13}C
^{13}C-NMR	Structure and purity verification	Meets requirement
m.p.	Conforms to standard	262-263 °C
Appearance	White powder	White powder

JOHN KUO, Ph. D.
Analytical & Quality Control
Supervisor

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CERTIFICATE OF ANALYSI

Product Name:
(Isotopic Label & Enrichment Specification)
SODIUM ACETATE
(1-13C, 99%) STERILITY/PYROGENICITY TESTED

Lot Number: PR-15759

Catalog Number: CLM-156-SP

Product Information

Chemical Purity Specification:	≥98%
Labeled CAS Number:	23424-28-4
Unlabeled CAS Number:	127-09-3
Molecular Weight:	83.0
Chemical Formula:	CH3*COONa
Storage:	Store at room temperature away from light and moisture.
Stability:	Stable if stored under recommended conditions.

Certification

Cambridge Isotope Laboratories, Inc. guarantees that this material meets or exceeds the specifications stated. Absolute identity as well as chemical and isotopic purities are assured by the use of unambiguous synthetic routes and multiple chemical analyses whenever possible.

Approved by: Deborah E. Costa
Deborah E. Costa, Quality Assurance

Quality Control Tests and Results

GC/MS for Isotopic Enrichment	99.1%
Karl Fischer Titration for Total Water Content	482 ppm
Heavy Metals Analysis	<10 ppm
Microbial Limits	Pass
pH Analysis	8.7
Endotoxin Test (LAL) of Bulk Lot	<0.03 EU/mg
Titration for Chemical Purity	99.5%
1H NMR for Chemical Purity	Pass
13C NMR for Identification	Conforms

Children's Hospital · St. Louis

Clinical Laboratories
One Children's Place
St. Louis, MO 63110

Chart Printed: **02/13/04 4:31 AM**
Admit Date: **07/22/2002**
Discharge Date:
Doctor: **Hamvas, Aaron**
Client: **Pediatrics Newborn Med NBM Study (SLCH client)**

Patient Name:
Med Record Number
Birthdate/Age/Sex: **/ Unknown / Unknown**
Patient Location:

MICROBIOLOGY - ROUTINE

PROCEDURE: Aerobic Culture (Routine)
SOURCE: Drainage
BODY SITE: Infusaport
FREE TEXT SOURCE:

COLLECTED: 02/12/04 1343
STARTED: 02/12/04 1400
ACCESSION: 04-043-003427

*** DIRECT SPECIMEN EXAMINATION ***
Stain
Cytospin gram stain shows:
No polymorphonuclear leukocytes seen.
No organisms seen.

REPORTED: 02/12/04 1614

Nur Palm Lot CR1261-Sp.

PROCEDURE: Aerobic Culture (Routine)
SOURCE: Environmental
BODY SITE: None
FREE TEXT SOURCE:

COLLECTED: 07/22/02 1030
STARTED: 07/22/02 1412
ACCESSION: 02-203-003676

*** FINAL REPORT***
No growth

REPORTED: 07/24/02 0922

MICROBIOLOGY - MYCOLOGY

PROCEDURE: Mycology Culture
SOURCE: Environmental
BODY SITE:
FREE TEXT SOURCE:

COLLECTED: 07/22/02 1030
STARTED: 07/22/02 1413
ACCESSION: 02-203-003721

*** FINAL REPORT***
Negative

REPORTED: 08/18/02 1232

* * * Interpretive Results * * *
Cultures are held for 4 weeks. They are examined daily for the first week, and weekly thereafter.

* Abnormal	A Alert	f Footnote	^ Corrected	L Low	H High	i Interp Data

Cumulative

Bio-Science Research Institute, Inc.

4813 Cheyenne Way
Chino, California 91710
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Fax (909) 590-8948

Director: Tae W. Kang, Ph.D
FDA Registration No.: 2022038
DEA Registration No.: RB0177887
www.bio-scienceresearch.com

TEST: Assay for Sodium Acetate and Potassium Palamitate

CLIENT: Washington Univ School of Med, Div of Newborn Med

SAMPLE: Isotope preparation

Sample Description: clear colorless liquid

date received: 2-13-04 date reported: 2-23-04

our work No.: Wash021304 your PO No.: 21310J

Method: Flame Photometric Raw Data Page: Wash

Results

Analytes	Results
Sodium Acetate	10.66 mg/ml
Potassium Palamitate	7.2 mEq/l

New Palm Lot CR 12261
Acu Lot. PR 13851

Authorized Signature Ph. D

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Director: Tae W. Kang, Ph.D
FDA Registration No.: 2022038
DEA Registration No.: RB0177887
www.bio-scienceresearch.com

TEST: LAL (Bacterial Endotoxin) Test

CLIENT: Washington Univ School of Med, Div of Newborn Med

SAMPLE: Isotope preparation

Sample Description: clear colorless liquid

date received: 2-13-04 date reported: 2-23-04

our work No.: Wash02304 your PO No.: 21310J

Method: Gel Clot Raw Data Page: Wash

Results

Less than 1 EU/ml

Authorized Signature Ph. D

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Director: Tae W. Kang, Ph.D
FDA Registration No.: 2022038
DEA Registration No.: RB0177887
www.bio-scienceresearch.com

TEST: Particulate Matter

CLIENT: Washington Univ School of Med, Div of Newborn Med

SAMPLE: Isotope preparation

Sample Description: clear colorless liquid

date received: 2-13-04 date reported: 2-23-04

our work No.: Wash021304 your PO No.: 21310J

Method: Microscopic Raw Data Page: Wash

Results

Conforms

Authorized Signature Ph. D